DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

Office of the Director

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NATIONAL INSTITUTES OF HEALTH

Office of the Director

For carrying out the responsibilities of the Office of the Director, National Institutes of Health, [$361,145,000, of which up to $10,000,000 shall be used to carry out section 217 of this Act] *$385,195,000*: *Provided*, That funding shall be available for the purchase of not to exceed 29 passenger motor vehicles for replacement only: *Provided further,* That the Director may direct up to 1 percent of the total amount made available in this or any other Act to all National Institutes of Health appropriations to activities the Director may so designate: *Provided further,* That no such appropriation shall be decreased by more than 1 percent by any such transfers and that the Congress is promptly notified of the transfer: *Provided further,* That the National Institutes of Health is authorized to collect third party payments for the cost of clinical services that are incurred in National Institutes of Health research facilities and that such payments shall be credited to the National Institutes of Health Management Fund: *Provided further,* That all funds credited to the National Institutes of Health Management Fund shall remain available for one fiscal year after the fiscal year in which they are deposited[: *Provided further,* That up to $500,000 shall be available to carry out section 499 of the Public Health Service Act]: *Provided further,* That of the funds provided $10,000 shall be for official reception and representation expenses when specifically approved by the Director of NIH[: *Provided further,* That a uniform percentage of the amounts appropriated in this Act to each Institute and Center may be utilized for the National Institutes of Health Roadmap Initiative: *Provided further,* That the amount utilized under the preceding proviso shall not exceed $176,800,000 without prior notification to the Committees on Appropriations of the House of Representations and the Senate: *Provided further,* That amounts utilized under the preceding two provisos shall be in addition to amounts made available for the Roadmap Initiative from the Director's Discretionary Fund and to any amounts allocated to activities related to the Roadmap Initiative through the normal research priority-setting process of individual Institutes and Centers].

[Departments of Labor, Health and Human Services and Related Agencies Appropriations Act, as enacted by the Consolidated Appropriations Act, 2005]

NATIONAL INSTITUTES OF HEALTH

Office of the Director

Language Analysis

Language Provision	Explanation
$361,145,000, of which up to $10,000,000 shall be used to carry out section 217 of this Act.	Amount updated for FY 2006 request and the authority to enter into other transactions is contained in section 216 and does not contain a dollar limitation.
Provided further, That up to $500,000 shall be available to carry out section 499 of the Public Health Service Act.	Funds are not requested for the Foundation for the National Institutes of Health in the FY 2006 President's Budget.
Provided further, That a uniform percentage of the amounts appropriated in this Act to each Institute and Center may be utilized for the National Institutes of Health Roadmap Initiative *Provided further,* That the amount utilized under the preceding proviso shall not exceed $176,800,000 without prior notification to the Committees on Appropriations of the House of Representations and the Senate: *Provided further,* That amounts utilized under the preceding two provisos shall be in addition to amounts made available for the Roadmap Initiative from the Director's Discretionary Fund and to any amounts allocated to activities related to the Roadmap Initiative through the normal research priority-setting process of individual Institutes and Centers].	This additional authority is not necessary to administer the Roadmap for Medical Research. NIH appreciates Congress' support for the Roadmap, and did propose to and will be administering it as the language describes. However, additional language is not needed, so it has not been repeated. In addition, such language could have the unintended effect of possibly restricting scientific decision-making if scientific advances required changes in the Roadmap for Medical Research within a fiscal year.

Justification

Office of the Director

Authorizing Legislation: Section 301 of the Public Health Service Act, as amended.

Budget Authority:

FY 2004 Actual		FY 2005 Appropriation		FY 2006 Estimate		Increase or Decrease	
FTEs	BA	FTEs	BA	FTEs	BA	FTEs	BA
561	$327,089,000	586	$358,046,000	599	$385,195,000	13	$27,149,000

This document provides justification for the Fiscal Year 2006 activities of the Office of the Director (OD), including HIV/AIDS activities. A more detailed description of NIH-wide Fiscal Year 2006 HIV/AIDS activities can be found in the NIH section entitled "Office of AIDS Research (OAR)."

Introduction

The OD provides leadership, coordination, and guidance in the formulation of policy and procedures related to biomedical research and research training programs. The OD coordinates NIH's extramural and intramural research activities; science policy and related ethical, legal, and social issues; technology transfer and intellectual property protection policies; health information dissemination and education functions; legislative activities; and oversight of the agency's stewardship of public funds.

The OD encourages and fosters NIH research and research training efforts in the prevention and treatment of disease and the promotion of health through program coordination offices that complement the efforts of the NIH Institutes and Centers (ICs). These offices focus on Acquired Immune Deficiency Syndrome (AIDS); women's health; disease prevention; science education; dietary supplements; rare diseases and disorders; and behavioral and social sciences research. While the OD provides the overall direction, coordination and oversight of these programs, the ICs manage the actual research operations. The OD is also responsible for coordinating trans-agency efforts for the NIH Roadmap for Medical Research. Initiatives under the NIH Roadmap are described at the end of this document and in the Congressional Justification Overview that appears in Volume I.

Office of AIDS Research

Introduction

The NIH Office of AIDS Research (OAR) coordinates the scientific, budgetary, legislative, and policy elements of the NIH AIDS research program and serves as the principal liaison with HHS, other federal agencies, and domestic and international governmental and non-governmental organizations on behalf of NIH AIDS-related research. The NIH represents the largest and most significant public investment in AIDS research in the world. Our response to the epidemic requires a unique and complex multi-institute, multi-disciplinary, global research program. Perhaps no other disease so thoroughly transcends every area of clinical medicine and basic scientific investigation, crossing the boundaries of the NIH Institutes and Centers. This diverse research portfolio demands an unprecedented level of scientific coordination and management of research funds to identify the highest priority areas of scientific opportunity, enhance collaboration, minimize duplication, and ensure that precious research dollars are invested effectively and efficiently. This is recognized in the unique role given the OAR in its authorizing legislation, the NIH Revitalization Act of 1993. That law establishes OAR as a model for trans-NIH coordination, vesting it with primary responsibility for overseeing all NIH AIDS-related research, and thus allowing NIH to pursue a united research front against the global AIDS epidemic.

Accomplishments

Comprehensive AIDS Research Plan and Budget: Each year, OAR oversees the Congressionally-mandated development of the comprehensive NIH AIDS-related research plan and budget, based on scientific consensus about the most compelling scientific priorities and opportunities that will lead to better therapies and prevention strategies for HIV disease. The planning process is inclusive and collaborative, involving the NIH institutes through a series of trans-NIH Coordinating Committees, as well as eminent non-government experts from academia, foundations, industry and the AIDS community. Historically, the Plan has established the NIH AIDS research agenda in the following Scientific Areas of Emphasis: Natural History and Epidemiology; Etiology and Pathogenesis; Therapeutics; Vaccines; and Behavioral and Social Science. As the epidemic evolved, OAR recognized the need to bring additional focus to a number of cross-cutting areas. The Plan now also includes: Racial and Ethnic Minorities; Women and Girls; Microbicides; HIV Prevention Research; International Research; Training, Infrastructure, and Capacity Building; and Information Dissemination.

The Plan is a critical document, as it serves as the framework for developing the annual AIDS research budget for each Institute and Center; for determining the use of AIDS-designated dollars; and for tracking and monitoring those expenditures. The law provides that the OAR shall allocate all appropriated AIDS research funds to the Institutes. This process allows the OAR to ensure that NIH AIDS-related research funds will be provided to the most compelling scientific opportunities, rather than distributed simply by a formula.

Trans-NIH Coordination: During the course of the year, OAR identifies scientific areas that require focused attention and facilitates multi-institute activities to address those needs. OAR fosters these efforts by designating resources to jump-start program areas by providing funds and supplements to the Institutes and Centers; establishing working groups or committees;

sponsoring workshops or conferences to highlight a particular research topic; and sponsoring reviews or evaluations of research program areas. For example, a number of years ago OAR identified microbicides research as an area needing additional attention. OAR established a Trans-NIH Microbicides Working Group, comprised of program staff of relevant institutes and offices; co-sponsored the first international conference on microbicides; spearheaded the development of an NIH Strategic Plan for Microbicides and a broader government-wide plan; and provided supplemental funds to the institutes to accelerate microbicide research. OAR also has placed high priority on research to address the disproportionate impact of the epidemic on racial and ethnic minority communities in the U.S. by directing increased resources toward new and innovative interventions that will have the greatest impact on these groups and efforts to improve research infrastructure and training opportunities for minorities.

International AIDS Research: OAR coordinates, monitors, and fosters plans for NIH involvement in international AIDS research and training activities. OAR established a new initiative and strategic plan for global research on HIV/AIDS aimed at significantly expanding our efforts to benefit resource- and infrastructure-poor nations. OAR has designated funds for the Institutes to expand clinical research internationally, including in the areas of microbicide development, identifying therapeutic approaches appropriate for international settings, vaccine research, and research capacity building.

Other OAR Activities: OAR supports Coordinating Committees for each area of program emphasis for AIDS research. These committees allow OAR to stay abreast of the scientific programs across the NIH, to foster collaboration and coordination, and to develop the annual NIH plan and budget. Congress has provided a transfer authority that permits OAR to move up to a total of 3 percent of AIDS research funds between institutes. OAR supports the Intramural AIDS Targeted Antiviral Program and the NIH AIDS Research Loan Repayment Program. OAR also supports a number of initiatives to enhance dissemination of research findings to researchers, physicians, institutions, communities, constituency groups, and patients, particularly in minority communities.

The FY 2006 budget request for the OAR is $60.899 million, which is the same as the FY 2005. The OAR budget justification for NIH AIDS research appears under a separate tab in this Congressional Justification.

The Office of Research on Women's Health

Introduction

The Office of Research on Women's Health (ORWH), established in 1990 within the Office of the Director, (a) advises the NIH Director on matters relating to research on women's health; (b) strengthens and enhances research related to diseases, disorders, and conditions that affect women; (c) ensures that research conducted and supported by NIH adequately addresses issues regarding women's health; (d) ensures that women are appropriately represented in biomedical and biobehavioral research studies supported by NIH; (e) develops opportunities for and supports recruitment, retention, re-entry, and advancement of women in biomedical careers; and (f) supports research on women's health issues. ORWH works in partnership with the NIH institutes and centers (ICs) to ensure that women's health research is part of the scientific framework at NIH and throughout the scientific community.

The FY 2006 ORWH budget request is $41.363 million, an increase of $0.148 million above FY 2005.

Science Advances

Preventing Cervical Cancer with an HPV Vaccine

Background: Globally, cervical cancer annually causes over 200,000 deaths and is the second most common cause of cancer mortality in women.[a] Virtually all cases of this cancer are attributable to a subset of human papillomaviruses (HPV), 50 percent from HPV16 and 10-20 percent from HPV18. An effective HPV vaccine should be able to reduce the incidence of these cancers by preventing HPV infection.

Advances: National Cancer Institute (NCI) investigators, with support from ORWH, have developed a method for producing an HPV vaccine composed of a single non-infectious protein from the virus. The scientists find: 1) multiple copies of the viral protein spontaneously assemble into empty shells (called virus-like particles or VLP) to which the immune system responds as though encountering the authentic virus; 2) the VLP vaccine is highly protective in animal papillomavirus models; 3) an HPV16 VLP vaccine is safe in people, in whom it induces a strong, systemic immune response with antibodies at the cervix, although menstrual cycle-dependent changes in antibody level are noted.

Implications: The prevention of cervical cancer is the main public health goal of the HPV vaccine trial. If the vaccine were 90 percent effective against these HPV types, it would result in about 150,000 fewer deaths per year worldwide. The vaccine would also be expected to reduce by 50 percent the one million cases of precancerous cervical lesions that require treatment.

Decreasing Cardiovascular Disease in Middle-Aged Women by Preventing Recurrent Episodes of Depression

Background: The Study of Women's Health Across the Nation is the first long term study of the natural history of the menopause transition. This study, which has received long-term support from the National Institute on Aging (NIA) and ORWH, is of high relevance to understanding healthy aging in midlife women of all races.

Advance: Researchers found that the risk of atherosclerotic plaque was more than double in women with a lifetime history of recurrent major depressive episodes, compared to women with no history of depression.

Implications: Prevention of recurrent episodes of depression may have benefits in preventing further progression of atherosclerosis, which contributes to the occurrence of coronary heart disease, the major cause of death in women.

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[a] Parkin, DM, Bray, F, Farley, J, Pisani, P. Estimating the world cancer burden: Globocan 2000. Int. J. Cancer 2001:94:153-6.

Accomplishments

Interdisciplinary Research and Career Development Programs in Women's Health
Background: ORWH has developed three interdisciplinary research and career development programs to further enhance Women's Health Research - The *Specialized Centers of Research (SCORs) on Sex and Gender Factors Affecting Women's Health,* which provide opportunities for interdisciplinary research to advance sex and gender factors in women's health, the *Building Interdisciplinary Research Careers in Women's Health (BIRCWH),* which supports young investigators in a mentored research environment to progress to independent investigator status in women's health or sex and gender research; and the Intramural Program on Women's Health . The intramural program was just launched in 2004.

Advances: These interdisciplinary programs proved successful in training and mobilizing scientists in diverse disciplines. Since 2000, a total of 177 scholars were trained, and a total of 634 articles were published as a result of the *BIRCWH* programs. Each SCOR promotes interdisciplinary collaborations and development of a research agenda bridging basic and clinical research on sex and gender factors underlying a priority health issue such as pain, urinary tract disease, pregnancy, and substance abuse. BIRCWH and SCOR programs jointly sponsored the first *NIH Women's Health Interdisciplinary Research Symposium* on October 4-5, 2004 to showcase the research that is being done as well as the success of our BIRCWH scholars. The Principal Investigators of both programs, as well as our BIRCWH Scholars, were brought together for this symposium providing an opportunity to network and exchange scientific insights across programs and research fields of pursuit.

The *SCOR* program made significant progress in the development of experimental methodology and the implementation and expansion of interdisciplinary research, especially sex and gender-specific factors in health and disease.

Implications: Both extramural programs were highly successful in increasing the scientific productivity of researchers from diverse fields of study in diverse areas of research related to women's health and to sex/gender factors in health and disease. They also contributed significantly to the scientific literature in these areas, and facilitated institutional commitment to interdisciplinary collaborations in basic and clinical research and to research to expand our knowledge about sex and gender comparisons that will enhance gender-specific health care for women and men. The intramural program is still in a preliminary phase but is expected to also enhance interdisciplinary research across the NIH scientific community.

New Initiatives

Benign Uro-Gynecological Conditions: In FY 2006, there will be a special emphasis on uterine fibroid research and the need for improved clinical and non-surgical alternatives for women with this condition. Research initiatives will be based on "Advances in Uterine Leiomyoma Research: Second NIH International Congress," sponsored by ORWH with ten ICs and sister DHHS agencies.

Prevention Research on Women and Girls: Evidence exists that many chronic health conditions have their origins in early life and young adulthood and result from unhealthy living, risky

behaviors, and non-adherence to screening and detection recommendations. ORWH will partner with NIH ICs and DHHS agencies to coordinate a scientific meeting on Prevention Research on Women and Girls, including the effects of dietary supplements, nutrition, exercise, obesity, weight patterns, and behavioral, social, and community factors on the susceptibility to, or protection from, disease. The conference proceedings will provide the basis for possible future research initiatives.

Office of Behavioral and Social Sciences Research

Introduction

The Office of Behavioral and Social Sciences Research (OBSSR) furthers the mission of NIH by emphasizing the role that behavioral and social factors and their interaction with biomedical variables play in health. The three main goals of the Office are to: (1) enhance behavioral and social sciences research and training; (2) integrate a biobehavioral perspective across NIH; and (3) improve communication among health scientists and with the public. Specifically, the major responsibilities of the Office include the following:

- providing leadership and direction to increase the scope of and support for behavioral and social sciences research and training at the NIH;
- advising key NIH officials on matters relating to behavioral and social sciences research;
- serving as the principal spokesperson on the importance of behavioral and social sciences research in the acquisition, treatment, and prevention of disease and disability;
- stimulating research in the behavioral and social sciences and interdisciplinary research;
- providing leadership in disseminating findings from behavioral and social sciences research;
- and sponsoring seminars, workshops, and conferences at the NIH and at national and international scientific meetings on behavioral and social sciences research.

Since its establishment in 1995, the Office has made significant progress in fulfilling each of its mandates, including organizing 35 trans-NIH funding activities, sponsoring 10 major conferences, co-sponsoring multiple conferences, workshops and symposia, as well as organizing and sponsoring training institutes and trans-NIH planning groups. The budget request for OBSSR in FY 2006 is $26.185 million, an increase of $0.94 million above the FY 2005.

Accomplishments

Expanding the Initiative on Mind-Body Interactions and Health. The Public Health Service has documented that many of the leading causes of morbidity and mortality in the US are attributable to social, behavioral, and lifestyle factors. Numerous studies have also documented that psychological stress is linked to a variety of health outcomes, including heart disease and decreased immune system functioning, and researchers and public health officials are becoming increasingly interested in understanding the nature of this relationship. In FY 1999, the NIH issued a Request for Applications (RFA) for Centers for Mind-Body Interactions and Health and subsequently awarded five P50 Center Grants. In anticipation of the termination of these grants in FY 2004, OBSSR, in cooperation with NIH Institutes and Centers (ICs), issued two Requests for Applications (RFAs) for *Mind-Body and Health Research Infrastructure or Development Programs* and a third RFA for regular research grants (R01). These RFAs resulted in the awarding of six center-like grants and six smaller developmental grants as well as 12 research

grants. OBSSR provided about $10.2 million and the ICs approximately $4 million in FY 2004 for these awards. OBSSR has worked with the ICs to issue a program announcement in FY 2005 calling for research grants on mind-body interactions and health.

Maintenance of Long Term Behavioral Change. Mounting evidence suggests the need for research that examines biopsychosocial processes and tests interventions designed to achieve long-term health behavior change. Research efforts funded by a recent OBSSR-coordinated RFA were successful in achieving a positive behavioral change during and immediately following the intervention phase. However, other research indicates that relapse rates for addictive behaviors such as substance abuse and tobacco use are very high. For example, most individuals who stop smoking cigarettes relapse within six months. Adherence to exercise, diet, and other health regimens is no better, despite the fact that initial success rates for various behavior change programs are very good. Thus long-term behavior change is as challenging, if not more so, than the initiation of behavior change. Past research efforts have typically focused on short-term behavioral change. In FY 2004, OBSSR implemented an initiative that encourages investigators to expand on the current theoretical base of change processes and intervention models, to expand our understanding of how change, once achieved, is maintained over the long term. The ten participating NIH Institutes and Offices have awarded twenty grants under this initiative including three new grants in FY 2005.

Health Literacy. *Healthy People 2010* established a national health objective to improve health literacy by the decade's end. DHHS' initiative, *Healthy People 2010*, defines health literacy as the capacity to obtain, process, and understand basic health information and services needed to both make appropriate health decisions and use such information and services to enhance health. As the sharing of relevant health information and the active participation in health care and health promotion efforts are dependent on health literacy, strengthening health literacy is a means to increase quality and years of healthy life and to eliminate health disparities. While many diseases and conditions can be prevented or controlled, too often people with the greatest health burdens have few fact-finding skills and the least access to health information. Moreover, health care providers may not be able to communicate effectively with these individuals. In the spring of 2004, OBSSR and several ICs issued a Program Announcement (PA) for research to increase the scientific understanding of the nature of the health literacy problem and its relationship to disparities in health outcomes and health communications problems and to test interventions to overcome the adverse consequences of low health literacy. Applications to this PA were received in FY 2005.

New Initiatives

Genetics, Social Environments, and Health. In-depth understanding of pathways to disease and preservation of good health necessitates the study of environmentally induced gene expression. Whether a particular gene is expressed and the degree to which it is expressed depends strongly on the physical and social environmental conditions experienced by the organism. Very little is known about how various characteristics of the social environment affect gene expression. Scientifically, the key task is to define the pathways that lead to disease. This requires, first, understanding how genes and related factors might be associated with the onset of particular disease outcomes and, second, tracking relevant mediating conditions. OBSSR and the National Human Genome Research Institute (NHGRI), leaders of trans-NIH effort to identify barriers and

opportunities for promoting research on "gene by social-environment" interactions, collaborated with the National Institute of General Medical Sciences (NIGMS) to support an Institute of Medicine study on the state of the science on gene-environment interactions, with a focus on social environments. The study will identify approaches and strategies to strengthen the integration of social, behavioral, and genetic research in this field and will address methodological issues, identify research gaps, recommend priorities for NIH research, and assess workforce, resource, and infrastructure needs.

Social and Behavioral Research on Health Disparities. OBSSR is leading a trans-NIH effort to convene a scientific conference on social and behavioral factors in health disparities. The goals of the conference are to (1) highlight the actual and potential contributions of behavioral and social sciences research to NIH's mission of reducing disparities in health, and (2) to identify areas requiring increased conceptual, empirical, and methodological development. The conference, to be held in FY 2006, will consist of a public conference and a private consultation session.

Strengthening Behavioral and Social Science in Medical Schools. An Institute of Medicine study on introducing social and behavioral sciences into medical school curricula concluded that the scientific evidence for the impact of behavior and social science on health is substantial. To apply this knowledge, future physicians must receive appropriate training during their medical education. Changes in medical school curricula to incorporate this field requires careful thought, planning, and development of clear objectives to best achieve the goals and overcome the obstacles. A committee was formed to review the approaches used by medical schools that have incorporated behavioral and social sciences into their curricula, develop a list of prioritized topics from the behavioral and social sciences for possible inclusion in medical school curriculum, and provide options for how changes in curriculum can be achieved. The committee issued a final report in 2004. In FY 2005, OBSSR released a RFA entitled *Strengthening Behavioral and Social Science in Medical Schools*, in collaboration with National Center for Complementary and Alternative Medicine (NCCAM), NCI, National Heart, Lung, and Blood Institute (NHLBI), National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), and NICHD, using the Academic Award Program (K07) of the NIH to develop behavioral and social science curricula for medical schools.

Social Work Research. Social workers focus on the creation of effective health, and mental health, prevention and treatment interventions for individuals to become more productive members of society. As providers of front line prevention and treatment services in the areas of aging, teen pregnancy, child abuse, and substance abuse, particularly in underserved communities, they are in a unique position to provide valuable research information on these complex social concerns. To provide the impetus and resources to fully incorporate social work's unique concepts and perspectives into the NIH research portfolio and to build the scientific base to be used by allied health professionals, OBSSR and other ICs developed a new PA released in FY 2005.

The Office of Dietary Supplements

Introduction

The Office of Dietary Supplements (ODS) was established in 1995 under the Dietary Supplement Health and Education Act (DSHEA). Its first Strategic Plan in 1998 identified five scientific and communications goals. Substantial increases in the ODS budget since 1999 were crucial in making significant progress toward these goals and in developing new areas; this triggered the need for ODS to update its Strategic Plan. The updated plan was completed early in 2004 and is available on the ODS Web site http://ods.od.nih.gov. The FY 2006 budget request for ODS is $27.078 million, an increase of $0.097 million above the FY 2005.

Accomplishments

Evidence-Based Reviews of Dietary Supplement Benefits and Safety. Report language in FY 2001 encouraged ODS to examine efficacy and safety of dietary supplements. Collaborating with the Agency for Healthcare Research and Quality (AHRQ) and its Evidence-Based Practice Center (EPC) network, we systematically built the knowledge base on benefits and safety of supplements and encourage research to fill gaps in knowledge.

- Report language in FY 2002 called for systematic review of literature related to the health benefits of omega-3 fatty acids with respect to heart disease and other disorders (http://ods.od.nih.gov/go/omega3ahrqreports). ODS worked with the National Heart, Lung, and Blood Institute (NHLBI) and other ICs to develop the task order for this review. ODS and NHLBI convened a working group to recommend further clinical research on omega-3 fatty acids and heart disease.
- Report language for FY 2004 called on ODS and National Center for Complementary and Alternative Medicine (NCCAM) to review evidence relating B-vitamins and antioxidant phytochemicals in berries to Alzheimer's and Parkinson's diseases, to determine future clinical research needs. This report will be done in 2005.

Dietary Supplement Analytical Methods and Reference Materials Program. Report language for FY 2002 called on ODS to develop, validate, and disseminate analytical methods and reference materials, coordinating these efforts among government agencies, academia, and the private sector. The methods validation effort uses an Interagency Agreement (IAG) with FDA to fund AOAC International, a scientific association committed to confidence in analytical results (www.aoac.org). The program, now in year 3 of a 5-year plan, has 38 methods in various stages of development and validation. ODS provides reference materials to support the US Pharmacopeia monograph program and has a 5-year IAG with the National Institute of Standards and Technology to produce Standard Reference Materials.

Dietary Supplement Research Centers. Initiated in FY 1999, this is a joint effort of ODS, NCCAM, and the National Institute of Environmental Health Sciences (NIEHS), with additional support from the National Institute of General Medical Sciences and Office of Research on Women's Health. Six centers are currently funded to conduct multidisciplinary research on botanicals. A Request for Applications (RFA) for re-competition was released in 2004. Applications in response to this RFA were reviewed in late 2004, with funding for the next 5-year cycle beginning in April 2005.

Co-funding of Research and Training. In FY 2004, ODS expanded its portfolio of co-funded grants by 35 percent over 2003. ODS co-funds 96 grants with 15 ICs for a total of $14.5 million, on topics that include development of methods for botanical supplement analysis, and a range of pre-clinical and clinical studies of dietary supplements. This includes funds for training of future scientists in dietary supplement research. ODS provides an additional $6.5 million toward IAGs with 7 Federal agencies.

Databases to Support Research on Dietary Supplement Use. ODS develops databases to enhance research. These include an analytically-substantiated database of dietary supplement ingredients of public health interest, and a database of supplement labels. ODS funds research on consumer motivations, usage patterns, and associations of supplement use with health indicators.

- *Dietary Supplement Analytically Substantiated Ingredient Database:* Studies to evaluate health effects of supplement intake require accurate data on product content. Such a database exists for conventional foods and is maintained by the USDA. ODS works with USDA to create a similar database for supplements.
- *Dietary Supplement Label Database:* ODS funds the Centers for Disease Control and Prevention (CDC) to maintain a database of supplement labels to assist with analysis of nutrient intake in the National Health and Nutrition Examination Survey (NHANES) and other surveys that monitor the health of the US population.
- *Research on Supplement Use:* ODS supports NHANES by funding measurement of blood metabolites to determine the nutritional status of persons who consume supplements and contracts with the Natural Marketing Institute to analyze population-wide surveys to assess consumer motivations for supplement use.

International Activities. Micronutrient deficiencies remain a problem in many parts of the world. ODS partners with other NIH ICs, such as the Fogarty International Center (FIC), to improve the quality of research needed to implement effective micronutrient assistance in diverse settings around the world. ODS and other ICs (NCCAM, FIC) co-sponsor an initiative to establish programs of rigorous, high-quality research on traditional medicine practices in the developing world.

Information and Communication Efforts. As part of its recent Strategic Planning process, ODS committed to expand its information, communication, and education products, particularly those aimed at consumers.

- The *International Bibliographic Information on Dietary Supplements* (IBIDS) database contains over 700,000 citations of worldwide published papers on dietary supplements.
- The *Computer Access to Research on Dietary Supplements* (CARDS) database details research studies on dietary supplements funded by the Federal government; from 1999-2003, more than 2200 projects were funded by NIH, covering research on more than 300 supplements.
- The *Annual Bibliography of Significant Advances in Dietary Supplement Research* provides a snapshot of the scientific literature for the previous year; the 2004 issue included 25 papers, selected from over 350 nominations in the peer-reviewed literature, on supplements related to cancer, bone health, heart health, inflammation, and early growth.

- ODS has commissioned a review of its communications program to provide a comprehensive analysis of its current efforts, recommendations for future areas of focus, and an evaluation plan for ongoing assessment and improvement.

New Initiatives

Evidence-Based Review Program: In collaboration with the NIH Office of Medical Applications of Research and other NIH ICs and Federal agencies, ODS is sponsoring an NIH State-of-the-Science Conference on the Role of Multivitamins/Multiminerals to Prevent Chronic Disease.

Dietary Supplement Label Databases: Senate Report language for FY 2005 called on ODS to contract with industry nonprofit foundations to develop, create, update, maintain, and make publicly available a comprehensive database of supplement labels. ODS is developing a request for proposals for this resource.

Bioactive Components of Food and Dietary Supplements: ODS, along with several ICs and other Federal agencies, formed an ad hoc Working Group to undertake the tasks of defining bioactive components and exploring approaches to evaluating their significance in health promotion and disease prevention. A *Federal Register* notice[b] was issued to seek public comment on the definition of bioactive components. Comments will be used to shape the agendas of public meetings, and develop approaches to assess the health effects of these substances.

International Activities: With increasing world-wide use of dietary supplements, fortified foods, and so-called "functional" foods, the need for an internationally harmonized approach for a science-based risk assessment process has become apparent. ODS and NIEHS funded an agreement with the World Health Organization to address this in a systematic, transparent way and to establish international agreement on developing upper limits for nutrients and related substances. Results will be useful in providing sound scientific information to international food standard-setting activities and to nation states in developing national policies and guidance, as well as identifying research needs.

The Office of Rare Diseases

Introduction

The Office of Rare Diseases (ORD) was established in 1993 and legislated by Public Law 107-280, the Rare Diseases Act of 2002.[c] A rare disease is a disease or condition affecting fewer than 200,000 persons in the United States. An estimated 25 million people in the United States have a rare disease. The goals of ORD are to stimulate and coordinate research on rare diseases and to support research to respond to the needs of patients who suffer from the more than 6,000 rare diseases known today. The budget request for FY 2006 for ORD is $15.705 million, an increase of $0.056 million above the FY 2005 level.

[b] Vol 69, No 179: Sept 16, 2004, pp 55821-55822
[c] Public Law 107-280, the Rare Diseases Act of 2002, Sec 2 (a) (2).

Accomplishments

Extramural Research Program

- *Rare Diseases Clinical Research Network*. Since FY 2004, ORD together with the NIH Institutes supports ten Rare Diseases Clinical Research Consortia and a central Data and Technology Resources Coordinating Center. The network consists of more than 70 sites and includes 30 patient support organizations for almost 50 rare diseases. The vast distribution of research locations will make investigational treatments more accessible to patients with rare diseases. The network systematically collects clinical information to develop biomarkers and new approaches to diagnosis, treatment, and prevention of rare diseases, and to provide training of new clinical research investigators. In FY 2004, the NIH increased the number of consortia from seven to ten and added support for pilot studies and demonstration projects available to all consortia. The central data and technology coordinating center has established websites for the network and individual consortia. Thirty-three clinical protocols are under development. The collaborating patient support groups established their own coordinating coalition which is represented on the steering committee.

- *Solicitations for Rare Diseases Research Activities.* In addition, ORD supported the following extramural research activities in collaboration with NIH Institutes and Centers (ICs) in FY 2004:
  - A program announcement with the National Heart Lung and Blood Institute (NHLBI) for pilot studies, demonstration projects, and/or exploratory research studies in rare diseases.
  - A request for applications published with the National Human Genome Research Institute (NHGRI) for applications for research training grants in genomics and proteomics.
  - A program announcement with the National Institute of Neurological Diseases and Stroke (NINDS) to improve treatment outcomes for lysosomal storage disorders.
  - A joint program announcement with 11 ICs to provide support for the planning of Phase III clinical trials.

Intramural Research Program. The Rare Diseases Intramural Research Program is a collaborative effort between the ORD and the NHGRI at the NIH Clinical Center. The program includes evaluating gynecological aspects of rare diseases, evaluating undiagnosed inborn errors of metabolism, initiating select clinical research protocols, and establishing a pilot program to provide patient travel free of cost through Angel Flight/Mercy Medical for rare diseases evaluation and participating in clinical protocols. In addition, ORD supported *Bench to Bedside Awards* in FY 2003. ORD co-funded with NIH ICs eleven Bench-to-Bedside awards at the NIH Clinical Center. Intramural scientists at the NIH partner with colleagues on basic science-clinical research collaborations that focus on rare diseases.

Genetic and Rare Diseases Information Center. The ORD continues to support with the NHGRI Genetic and Rare Diseases Information Center (GARD). GARD staff provides information to patients and their families, health professionals, researchers, and to the public. In FY 2004, the information center became more accessible to minority and under-served populations through services in Spanish and a more user-friendly web-based approach. Since its inception in September 2001, GARD has responded to more than 10,000 inquiries for more than 3,000 rare diseases.

Scientific Conferences Program. In FY 2004, ORD co-funded 86 national and international scientific conferences in collaboration with NIH Institutes and Centers, identifying scientific opportunities for rare diseases research. Examples of rare diseases include childhood cancers, bone marrow failure, sickle cell disease, congenital heart disease, dystonias (rare, severe movement disorders with sustained muscle contractions), pediatric stroke, neurofibromatosis (a set of genetic disorders which cause multiple tumors to grow along various types of nerves) and primary lateral sclerosis (a rare neuromuscular disease characterized by progressive muscle weakness).

Public Input. In FY 2004, ORD continued to support regional workshops for leaders of patient advocacy groups across the nation about all aspects of research and research opportunities in NIH's extramural and intramural rare diseases research programs. These workshops enable national organizations to become partners in research endeavors and provide public input into ORD and NIH future research plans. Also, to gain additional public input, ORD held focus group meetings with leaders of patient advocacy groups at the annual meetings of the National Organization for Rare Disorders and the Genetic Alliance.

New Initiatives

In 2004, ORD began a number of major initiatives that will come into fruition in the coming years.

- A *Trans-NIH Rare Diseases Research Working Group* with membership from NIH ICs. The working group is developing plans for a conference to assess rare disease biospecimen collection, storage, and delivery issues that impede research on rare diseases. Other issues include the development of genetic tests and a conference on amyloidosis. Amyloidosis is a group of disabling and life threatening diseases in which one or more organ systems in the body accumulate deposits of abnormal proteins.
- The National Human Genome Research Institute, the ORD, and The National Council of La Raza's Institute for Hispanic Health, will partner in a pilot education project to demonstrate effective ways to reach Latino communities with information about genetic and rare diseases.
- The ORD will participate in a web site user satisfaction survey to further improve the outreach to and delivery of information to patients with rare diseases and their families.
- In collaboration with NHGRI, the ORD intramural research program initiated a program to establish, with Clinical Laboratory Improvement Act-certified laboratories, molecular diagnostic tests for specific rare diseases. The ORD/NHGRI expects to increase the development of diagnostic/genetic tests for research to up to 25 annually to meet the needs of intramural research investigators, patients with rare diseases, and their families. These tests will be made available by the developing laboratory within six months to the general public.

Science Education Activities

Introduction

The Office of Science Policy (OSP), through its Office of Science Education (OSE), coordinates science education activities at the NIH and develops model science education programs. OSE works to advance the NIH mission by: creating programs to improve science education in

schools; creating programs to advance public understanding of medical science, research, and careers; promoting NIH educational resources and programs; and advising NIH leadership about science education issues. The majority of OSE programs and resources are developed for and targeted to K-12 science teachers. Additional programs and resources target the public, including middle school and high school students, underserved communities, women, and minorities.

Current Activities & Initiatives (Selected)

The OSE's most important activity is the development and distribution of the NIH Curriculum Supplements and related professional development activities. These National Science Education Standards-based K-12 supplements are free, ready-to-use, interactive teaching units that result from the unique partnering of NIH scientists, teachers, and expert curriculum developers. They incorporate the best of both science and education communities, and are intended to use NIH research to teach scientific concepts and supplement classroom materials that are out-dated. Approximately 140,000 NIH curriculum supplements have been distributed to K-12 science teachers, college professors and home-schoolers in all 50 states, the District of Columbia, Puerto Rico, U.S. Pacific Island territories and Department of Defense schools overseas.

The OSE Web site (http://science.education.nih.gov) continues as a major means of informing teachers nationally about NIH resources for science instruction. In the past three years, traffic on the site increased nearly six-fold, from about 6,500 to 39,600 users per month. The OSE Web site includes a unique career exploration section, *LifeWorks,* for middle and high school students, their parents, teachers, and career guidance counselors (http://science.education.nih.gov/LifeWorks). Launched in FY 2003, *LifeWorks* provides in-depth career information on over 100 health and medical science-related careers. Users can search the site and generate a customized list of careers that matches their skills and interests. Career-specific information includes educational requirements, recommended high school courses, salary projections, job outlook, training and certification requirements, related careers, and references for further information.

OSE has established a Diversity Workgroup (DWG) – a team dedicated to increasing the participation of minority and underserved populations in all OSE programs. In FY 2006, the DWG plans to pursue collaborations with offices and organizations (such as the Office of Equal Opportunity and Diversity Management, NIH) to develop new programs and explore strategies to expand existing programs targeting underserved and minority populations.

The budget request for OSE in FY 2006 is $3.878 million, an increase of $0.014 million over FY 2005.

Loan Repayment and Scholarship Programs

Introduction

NIH Loan Repayment Programs are a vital component of our nation's efforts to attract health professionals to careers in clinical, pediatric, health disparity, or contraceptive and infertility research.

Accomplishments

FY 2004, the NIH continued to support loan repayment and scholarship programs that are authorized by Congress. Loan repayments are supported for up to $35,000 per year plus Federal tax reimbursements at the rate of 39 percent of loan repayments as well as additional State and local taxes. Scholarship programs provide up to $20,000 per year.

- The NIH Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds (CR-LRP) awarded 1 two-year contract and sixteen one-year renewal contracts at a cost of $.551 million. For FY 2005, the CR-LRP plans to award contracts to 3 individuals entering into initial two-year contracts, and 15 contracts to individuals entering into one-year renewal contracts at a cost of $.725 million.
- In FY 2004 the NIH awarded $4.875 million to 75 individuals under the Loan Repayment Program for Research Generally (GR-LRP). Awards were made to fund 49 initial three- year contracts and 26 one-year renewal contracts to participants who are physicians or scientists engaged in either basic or clinical research activities at the NIH. For FY 2005, the GR-LRP plans to award contracts to 52 individuals entering into initial three-year contracts, and 31 contracts to individuals entering into one-year renewal contracts at a cost of $4.906 million.
- In FY 2004, the NIH supported the Undergraduate Scholarship Program for Individuals from Disadvantaged Backgrounds (UGSP) with scholarship awards and funding for service pay-back in the amount of $.838 million to 23 undergraduate students and 13 post baccalaureate students. For FY 2005, the UGSP plans to award scholarships and provide funding for summer internship service pay-back for 20 individuals and provide funding for 11 individuals performing one-year service pay-back at a cost of $.800 million.

New Initiatives

In FY 2006, the budget request is $7.213 million, an increase of $0.026 million over the FY 2005. The funding will be used for 19 awards under the Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds, 20 awards for the Undergraduate Scholarship Program for Individuals from Disadvantaged Backgrounds, and 89 awards under the Loan Repayment Program for Research Generally.

AIDS Research Loan Repayment Program

Introduction

In FY 2004 the NIH awarded $.271 million to seven individuals under the AIDS Research Loan Repayment Program (AIDS-LRP). Awards were made to seven health professionals, representing six recipients who entered into 1-year renewal contracts and one researcher who entered into an initial 2-year contract. For FY 2005, the AIDS-LRP plans to award three contracts to individuals entering into initial 2-year contracts, and thirteen contracts to individuals entering into 1-year renewal contracts at a cost of $.610 million.

New Initiatives

In FY 2006, the OAR request includes $.610 million for the AIDS LRP. The funding will be used to award contracts to 16 health professionals conducting AIDS research.

NIH Roadmap for Medical Research

Introduction

The NIH Roadmap for Medical Research is a set of trans-NIH research initiatives that are designed to accelerate the pace of discovery and improve the translation of research findings into healthcare interventions for public benefit. Under the Roadmap, there are 28 initiatives that fall under three themes: *New Pathways to Discovery, Research Teams of the Future*, and *Re-Engineering the Clinical Research Enterprise*.

The NIH Roadmap for Medical Research activities are centrally coordinated under the leadership of the Director, NIH and include science, budget, communication, evaluation, and policy elements of the related initiatives. The organizational structure for implementation allows for agency-wide input and communication. The 28 initiatives are led by nine implementation working groups, each co-chaired by institute and center (IC) directors. Two committees facilitate implementation. The Roadmap Implementation Coordination Committee provides overall governance and includes the co-chairs of the working groups and senior leadership in the Office of the Director. The Roadmap Institute and Center Liaisons are comprised of representatives from each IC. The budget request for NIH Roadmap for Medical Research in FY 2006 is $83.0 million, an increase of $23.280 million over the FY 2005.

Accomplishments

New Pathways to Discovery. Under this theme, the Roadmap seeks to identify and study the complex networks of cellular machinery at the levels of proteins, metabolites (lipids, carbohydrates, and amino acids), molecules, and even atoms. NIH already is pursuing several "pathways of discovery" through networked centers for exploration. The National Technology Centers for Networks and Pathways focus on development of tools for measuring protein activity and interaction. The Molecular Libraries Screening Centers seek to identify novel small molecules with potential as tools (biochemical probes) for investigating cellular pathways. The probes successfully screened under this initiative will be housed in new Small Molecule Repository for access by the scientific community. The scientific community and the public will have access to data on molecular structure through the recently launched PubChem website. The Molecular Imaging Probes initiative is developing additional tools that can portray cellular components and events at higher magnitudes of specificity and sensitivity than is possible with current technology. Also, the Roadmap is supporting the emerging field of metabolomics by developing technology to identify and measure cellular metabolites. Nanomedicine Concept Development Awards are planning for the development of formal centers that will explore the creation of materials and devices at the level of molecules and atoms to cure disease or repair damaged tissues. Management and the analysis of the wealth of bioinformation will be supported by newly established National Centers for Biomedical Computing.

Research Teams of the Future. Initiatives under this theme will prepare researchers to intellectually extend themselves beyond their research disciplines and will foster new collaborations. Academic and research institutions are focusing efforts on creating interdisciplinary research training programs, workshops, and courses as catalysts for development of new scientists, new science teams, and new scientific disciplines. Of particular

emphasis are initiatives facilitating the integration of quantitative, environmental, and behavioral sciences with biomedicine. The NIH Director's Pioneer Award funds bold, high-risk research with potential for momentous conceptual and technological breakthroughs. Critical to all of these efforts (at both the trans-agency and academic institutional levels) is the utilization of existing administrative best practices and lowering organizational barriers that hinder collaboration and integration.

Re-engineering the Clinical Research Enterprise. To speed the translation of scientific discoveries into health care interventions, the NIH Roadmap has efforts underway to improve clinical network capabilities and embrace a growing "community of research." The National Electronics Clinical Trials and Research Network (NECTAR) will streamline clinical research through standardized data reporting and data- and sample-sharing. The Roadmap also is developing a network to create a comprehensive, integrated approach to the collection, storage, and management of data on patient-reported outcomes (symptoms) across patients from diverse populations with a wide variety of chronic diseases. The Patient-Reported Outcomes Measurement Information System (PROMIS) network also will develop better ways to measure subjective patient-reported symptoms such as pain and fatigue. Currently in the conceptual stage, Regional Translational Research Centers aim to speed the pace at which clinical research develops into clinical intervention by providing one-stop shopping for sophisticated advice and resources such as expertise in biostatistics, clinical pharmacology, pharmacogenetics, and genetics. In addition, several efforts are underway to train and re-train clinical researchers. Initiatives range from predoctoral training programs to plans for establishing a National Clinical Research Associates (NCRA) program, a program that will help increase the number of clinical investigators and diversify the settings in which clinical research is conducted. Through NCRA, community-based healthcare practitioners will be trained to participate in research and recruited to refer and follow their patients in clinical research. This also will position them to rapidly disseminate advances in evidence-based care.

Concurrent with these efforts, the Clinical Research Policy Analysis and Coordination program (CRpac) is examining the regulatory and policy environment in which clinical research is being conducted and will work with other agencies to harmonize and streamline requirements to enable more effective and conducive research-management and oversight. The efforts to re-engineer the clinical research enterprise have also stimulated the establishment of the NIH Public Trust Initiative, involving the NIH Director's Council of Public Representatives and other members of the public at large.

New Initiatives

New solicitations for FY 2006 are planned within each of the three theme areas of the NIH Roadmap for Medical Research and build upon the programs and activities established in FY 2004 and FY 2005.

Molecular Libraries and Imaging. The High-Throughput Molecular Screening Assay Development solicitation will be reissued and a new solicitation, Novel Preclinical Tools for Predictive ADME-Toxicology, will be announced in FY 2006. The latter solicitation aims to improve methods used to test compounds for various properties including absorption, distribution, metabolism, excretion (ADME), and toxicity. Better ability to predict the profile of

chemical compounds will prevent some of the trial-and-error of clinical testing. In addition the NIH Imaging Probe Development Center, implemented within the intramural research program, will be fully operational and begin servicing the extramural research community in FY 2006. This center, designed to interact with other ongoing Molecular Libraries and Imaging Roadmap initiatives, will generate novel imaging probes and producing "known" or published imaging probes for which there is no commercial supply.

Building Blocks, Biological Pathways: Standards and Critical Reagents for Proteomics. Proteomics is the systematic study of proteins and their complex interactions in a cell or organism. Because proteomics is a new and complex scientific field, it is crucial to establish standards that will enable proteomic data from different laboratories to be easily shared, compared, and evaluated. FY 2006 initiatives will support research to establish needed standards and develop new statistical methods and software for analysis of proteomic data and evaluation of the quality of these data. New chemical agents (reagents) will also be critical for proteomic research, and NIH is planning to support the development of new technologies to produce such reagents.

Nanomedicine Development Centers. Solicitations for these Centers will be announced in FY 2005 and FY 2006. The Nanomedicine Development Centers will develop tools and concepts to characterize components of cells at the molecular level. The initial focus is on filling gaps in our ability to measure precisely the physical characteristics of nanoscale cellular components, characteristics such as their exact quantities, variations, locations, timescales, interactions, affinities, force generation, flexibility, and internal motion. The eventual goal is to gain the ability to control and manipulate cellular components at the molecular level to cure disease and repair tissue.

Interdisciplinary Research. The analytic strategies necessary for the integration of the behavioral and social sciences with biomedical, computational, physical and engineering sciences have not yet been articulated. In FY 2004, the Roadmap sponsored two initiatives to work toward such strategies - Supplements for Methodological Innovations in the Behavioral and Social Sciences and Meetings and Networks for Methodological Development in Interdisciplinary Research. In FY 2006, NIH plans to build on the base of research that those initiatives will generate by holding the Interdisciplinary Technology and Methods Summit. This conference will focus on topics such as pain, fatigue, and obesity that are in need of an interdisciplinary approach that integrates the behavioral, social and biomedical sciences.

High-Risk Research. In FY 2006 the NIH Director's Pioneer Awards, designed to encourage exploration of high risk, high impact ideas by investigators with exceptionally creative abilities, will be in its third cycle. Awardees are expected to commit the major portion of their effort to activities supported by this award.

Re-engineering the Clinical Research Enterprise. Moving beyond the planning stage, a solicitation for formal Regional Translational Research Centers will be issued in FY 2006. These centers would provide NIH-funded researchers with state-of-the-art expertise and resources in support of research at the interface of the bench and the bedside. Also in FY 2006, current efforts to inventory existing clinical research networks and the test approaches to

enhance the clinical research informatics infrastructure will culminate in the launch of the National Electronics Clinical Trials and Research (NECTAR) network. This network will enable standardized data reporting and data- and sample-sharing among studies. In addition, with the development of a feasible model for the National Clinical Research Associates (NCRA) Program, various elements of the model will be pilot-tested in FY 2006, followed by the design and implementation of the full NCRA Program.

The Director's Discretionary Fund

In FY 2006 the NIH Director will continue to maintain a Director's Discretionary Fund (DDF) to allow the Director to respond quickly to new and emerging high-priority research opportunities and health needs. The DDF request for FY 2006 is $93 million, of which $83 million is for the NIH Roadmap for Medical Research. This is an increase of $23.560 million over the FY 2005.

Office of Portfolio Analysis and Strategic Initiatives

With the growth and increasing complexity of the agency, NIH has moved aggressively to transform its management strategies and decision-making processes. To harmonize and better coordinate decisions that may affect the entire agency, the NIH director established in 2003 the new NIH steering committee composed of 9 institute directors. This was followed by the elimination of numerous standing or ad hoc management committees now replaced by five working groups (management and budget, extramural affairs, intramural affairs, IT and Facilities), thus greatly streamlining the decision making process and insuring clearer accountability across all corporate agency function while preserving the autonomy of ICs in their mission specific areas.

The agency is successfully engaging in trans-NIH initiatives such as the Roadmap, the Trans-NIH Obesity Research Plan and the emerging Neurosciences Blueprint. It is, however, time to focus additional attention to creating better institutional tools to analyze, assess and manage the NIH wide research portfolio and to provide better information tools to support priority setting decisions in areas of common interest to all ICs. With the growth of the agency, IC based programs need to have access to more consistent information to enable greater synergy when appropriate and to have more established mechanisms to plan their research investments, especially those which require coordination across multiple ICs. New analytic tools and systems need to be developed and implemented as part of an improved executive decision support system to improve the management of our large and complex scientific portfolio. This will allow NIH to more efficiently address important areas of emerging scientific opportunities and public health challenges. A new organizational structure will be established and staffed for this purpose.

In FY 2006, the NIH plans to create a new office within the Office of the Director -- the Office of Portfolio Analysis and Strategic Initiatives (OPASI) -- which will provide tools to facilitate planning for trans-NIH initiatives, including an improved process for collecting IC data on expenditures on various diseases, conditions, and research fields, and improvements in data about burden of disease. The office will also develop, with input from the ICs, common processes and formats, where necessary, for the conduct of NIH-wide planning and evaluation. For trans-NIH planning efforts, the office will seek broad public input -- from the public, health

care providers, policymakers, and scientists -- in addition to soliciting advice from within NIH. The office will also coordinate and make more effective use of the NIH-wide evaluation process. The budget request for OPASI is $2 million.

Other Areas of Interest

As part of the OD Operations, several OD offices such as the Office of Extramural Research, the Office of Intramural Research, the Office of Science Policy (OSP), and the Office of Management provide advice to the NIH Director, policy direction to the NIH research community, and administer centralized support services essential to the daily operation of the NIH. Within the OSP, the Office of Biotechnology Activities coordinates the functions of the Recombinant DNA Advisory Committee; the Secretary's Committee on Genetics, Health, and Society; the Secretary's Advisory Committee on Xenotransplantation, and the National Science Advisory Board for Biosecurity. The budget request for these operational offices for FY 2006 is $107.874 million, an increase of $1.651 million over the FY 2005.